K 063195

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
Valleylab LigaSure Advance™

1. Submitter Information

NOV 2 9 2006

Valleylab
5920 Longbow Drive
Boulder, CO 80301
Contact: Charles Copperberg
Telephone: 303-530-6469

Date summary prepared: October 18, 2006

2. Name of Device

Trade or Proprietary Name: LigaSure Advance™

Common Name: Monopolar and Bipolar Laparoscopic Electrosurgical Instrument

Classification Name:
- Electrosurgical Cutting and Coagulation Device and Accessories, and
- Gynecologic Electrocautery and Accessories

3. Predicate Devices

The Valleylab LigaSure Advance™ is substantially equivalent to the Valleylab LigaSure™LS1500 (K031011 and K043273) and the Valleylab Laparoscopic Electrode E2774-28 (K904560 and K964175).

The LigaSure Advance™ and the LigaSure™ LS1500 are used in laparoscopic surgery to seal vessels by the application of RF energy to the vessels and tissues interposed between the jaws of the instrument. Both incorporate a mechanical cutter to cut the tissue after sealing.

In addition, the LigaSure Advance™ also includes a monopolar electrode extending from one of the jaws of the device which can be used for monopolar dissection of tissue planes similar to the Valleylab Laparoscopic electrode, E2774-28.

4. Device Description

The LigaSure Advance™ is a 5mm laparoscopic vessel sealer and divider with integrated monopolar capability for energy-based dissection. The Valleylab LigaSure Advance™ is for use only with the Valleylab ForceTriad™ energy platform (electrosurgical generator), reference 510(k) notification K051644. The device will be offered in two lengths, 34 cm and 44 cm.

The LigaSure Advance™ device will be used to seal vessels, including lymph vessels, up to and including 7mm in diameter and tissue bundles. The sealed vessels and other tissue structures may be divided by the deployment of a mechanical knife that will reside within the shaft of the instrument and extends forward in a slot within the jaws when actuated by a mechanism residing within the handle of the device.

The monopolar capabilities of the device will be used to electrically dissect through tissue planes and to create openings in bowel (enterotomies) and stomach (gastrotomies). This is accomplished through a small electrode that protrudes from the distal end of one of the jaws of the device.

The controls for the device are all located on the handle. The instrument attaches to the generator with "smart" connectors, that identify the instrument type to the LigaSure generator, and a ten (10) foot cable. The instrument is supplied sterile for single-use.

5. Intended Use

The Valleylab LigaSure Advance™ is a 5mm laparoscopic, electrosurgical instrument that incorporates both monopolar and LigaSure™ tissue fusion (bipolar) functionality. It is intended for use with the Valleylab ForceTriad™ energy platform (electrosurgical generator)in general and gynecological, laparoscopic, surgical procedures where ligation and division of vessels, including lymph vessels, is desired. The monopolar feature of the instrument will be used where electrical dissection through tissue planes and creation of enterotomies or gastrotomies is desired.

The LigaSure function of the instrument creates a seal by the application of RF electrosurgical energy to vascular structures interposed between the jaws of the instrument. The sealed vessels and other tissue structures may be divided by the deployment of a mechanical knife that will reside within the shaft of the instrument and extends forward in a slot within the jaws.

Indications for use include general and gynecological, laparoscopic surgical procedures (including urologic, vascular, thoracic and thoracoscopic) where electrosurgical ligation and division of vessels, including lymph vessels, is performed. These procedures include: laparoscopic gastric bypass, laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, laparoscopic colectomy, adhesiolysis, oophorectomy, etc.

The Valleylab LigaSure Advance™ can be used on vessels up to and including 7mm diameter and tissue bundles as large as will fit in the jaws of the instrument.

The Valleylab LigaSure Advance™ has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

6. Summary of Technological Characteristics

The LigaSure Advance™ has the same basic technological characteristics as the predicate LigaSure device and the laparoscopic electrode noted above. The LigaSure

Advance™ will seal vessels (including lymph vessels) using bipolar RF energy and can mechanically divide the sealed areas or tissue with a mechanical cutting device incorporated into the shaft and jaws. In addition, the device also incorporates a monopolar electrode on one jaw for electrosurgical division of tissue.

7. Performance Data

Performance testing and pre-clinical studies were performed to ensure that the LigaSure Advance™ functions as intended, and meets design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate devices, and meets safety and effectiveness criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Valleylab, Inc.
% Mr. Charles Copperberg
Manager, Regulatory
5920 Longbow Drive
Boulder, Colorado 80301-3299

NOV 2 9 2006

Re: K063195
Trade/Device Name: LigaSure Advance™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 19, 2006
Received: October 20, 2006

Dear Mr. Copperberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063195

Device Name: LigaSure Advance™

Indications for Use:

The Valleylab LigaSure Advance™ is a 5mm laparoscopic, electrosurgical instrument that incorporates both monopolar and LigaSure™ tissue fusion (bipolar) functionality. It is intended for use with the Valleylab ForceTriad™ energy platform (electrosurgical generator) in general and gynecological, laparoscopic, surgical procedures where ligation and division of vessels, including lymph vessels, is desired. The monopolar feature of the instrument will be used where electrical dissection through tissue planes and creation of enterotomies or gastrotomies is desired.

Indications for use include general and gynecological, laparoscopic surgical procedures (including urologic, vascular, thoracic and thoracoscopic) where electrosurgical ligation and division of vessels, including lymph vessels, is performed. These procedures include: laparoscopic gastric bypass, laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, laparoscopic colectomy, adhesiolysis, oophorectomy, etc.

The Valleylab LigaSure Advance™ can be used on vessels up to and including 7mm diameter and tissue bundles as large as will fit in the jaws of the instrument.

The Valleylab LigaSure Advance™ has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR801 Subpart D) (21CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Res[illegible]
and Neurological Device[illegible]

(Posted November 13, 2003)

510(k) Number K063195